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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,966	10/31/2001	Richard A. Shimkets	15966-551CON S-2 (CURA-51	7979

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,966	SHIMKETS ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-15,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-15,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2004 has been entered.

Response to Amendment

2. Claims 2-5 and 12-15 have been amended and claims 18-19 have been added as requested in the amendment filed on March 01, 2004. Claims 1-8, 10-15 and 18-19 are pending in the instant application.

Claims 1-8, 10-15 and 18-19 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on June 30, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

6. Claims 1-8, 10-15 and 18-19 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 9 of Paper No. 8 and in section 5 in Paper mailed on October 30, 2003. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or encoding nucleic acids or their significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect. Therefore, the claimed invention does not meet the requirements of 35 U.S.C. § 101 as being useful.

Applicant traverses the rejection on the premises that "Applicants have demonstrated that SEC1/FGF is a FGF growth factor" (middle at page 2 of the Response) and belongs to FGF-10/FGF-7 subfamily of FGFs, which "have patentable utility in regulating inflammatory disorders, in addition to stimulating vascular cell and epithelial cell motility and differentiation" (bottom at page 3). Applicant also submits that "SEC1/FGF and hFGF10 interact with the same FGF receptor FGFR2 IIIb" as evidenced by Patturajan Declaration submitted on August 08, 2003 (bottom at page 2). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The instant specification provided the disclosure of DNA encoding SEC1/FGF polypeptide with structural similarities to fibroblast growth factors (FGF) family of polypeptides. According to the knowledge in the art, FGF are members of a large family of signaling molecules with many diverse biological activities both *in vitro* and *in vivo*, which include growth

and proliferation, differentiation, migration and survival of mesoderm-derived and neuroectoderm-derived cells (Manetti et al. 2000, Current Pharmacological Design, 6, pp. 1897-1924, see page 1897). Structural similarity between FGF members is ranging from 40 to more than 70% on amino acid sequence identity level (page 1898). Thus, based on the information presented in the instant specification, as filed, one skilled in the art would at most conclude that the novel disclosed SEC1/FGF of the instant invention could belong to the same family of proteins as FGF-10/ FGF-7 polypeptides or could be to some extent evolutionary related. As was fully explained in the previous communications of record, there are no known teachings in the art that would allow one to make a definite prediction of a protein function based solely on its structural similarities (54%) to a different protein with a broad range of different functions (human FGF10 precursor).

Applicant's argument that "[t]he FGF subfamily containing SEC1/FGF, FGF-10 and FGF-7 have substantial and specific utilities in regulating inflammatory disorders and stimulating vascular cell and epithelial cell motility and differentiation" (top at page 3 of the Response) is fully considered but is not persuasive because in view of the absence of any information regarding the specific biological significance of this particular SEC1/FGF one would not know which one, or combination of several, of the numerous activities of the FGF-7 or FGF-10 subfamily of polypeptides would be attributed to the instant asserted novel SEC1/FGF family member. For example, FGF-7 has been identified as being associated with proliferation and differentiation of epithelial cells in the liver, gastrointestinal tract and lung, as well as stimulation of liquid secretion in human fetal lung (page 1902 of Manetti et al. paper). FGF-10 has been shown to be a key factor in the limb outgrowth of vertebrates (page 1903 of Manetti et al. paper).

The instant specification, as filed, fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant SEC1/FGF is associated with any specific function, including biological activities of FGF-7 or FGF-10 subfamily of FGF. One skilled in the art readily appreciates that because the instant specification, as filed, has not linked the disclosed GR5LR with any specific disease state or disorder, including conditions associated with "inflammatory disorders, [or] stimulating vascular and epithelial cell motility and differentiation" (bottom at page 3 of the Response), there appears to be no scientific basis for concluding that SEC1/FGF would be useful for treating these diseases. One skilled in the art would be required to perform significant further research on the instant claimed invention in order to identify a specific biological activity of SEC1/FGF, its significance to a particular disease and, further, to what "use" any information regarding specific activity of SEC1/FGF could be put. Is SEC1/FGF a potential drug to stimulate epithelial cell differentiation, or could it be used as a marker for cancer, psoriasis or inflammatory disorders in general (see reasons of record in section 5 of Paper mailed on October 30, 2003)?

In the absence of knowledge of biological significance of this particular SEC1/FGF, there appears to be no apparent patentable use for the claimed encoding nucleic acids. Therefore, because the instant specification does not disclose a specific, substantial and credible use for the instant nucleic acids or the encoded protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

7. Claims 1-8, 10-15 and 18-19 are rejected under 35 U.S.C. 112, first paragraph for those reasons of record in section 10 of Paper No. 8 and in section 6 of Paper mailed on October 30, 2003. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ∋ 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.